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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,937	02/05/2004	Akira Hiraishi	80A 3510	6089

3713 7590 01/30/2007

KODA & ANDROLIA
2029 CENTURY PARK EAST
SUITE 1140
LOS ANGELES, CA 90067

EXAMINER	
POHNERT, STEVEN C	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,937	HIRAISHI, AKIRA	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the papers filed November 17, 2006. Currently claims 1-8 are pending. All arguments have been thoroughly reviewed but are deemed not persuasive for the reasons that follow.

This action is FINAL

Any objections and rejections not reiterated below are hereby withdrawn.

Maintained rejections

Information Disclosure Statement

1. The information disclosure statement filed 2/5/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Japanese document JP H10-501976 is provided, but lacks an English translation of specification or abstract, and is not considered.

Japanese document JP 2001-128879 is provided, but lacks an English translation of specification, and only the abstract was considered.

Response to Arguments

The applicant states, "Applicant respectfully submits that, 37 CFR 1.98(a)(2) only requires that Applicant submit a legible copy and states nothing concerning translation." This is not found persuasive because 37 CFR 1.98 (3)(i) states, "A concise explanation

of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein." There does not appear to be use a concise explanation as require by 37 CFR 1.98 (3)(i) in the disclosure.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rossau et al (US Patent 5945282).

The claimed invention is drawn to a method of identifying a microorganism by hybridizing to DNA corresponding to the ITS region of the microorganisms DNA. The specification teaches the ITS region exists between the 16S rRNA and the 23S rRNA (see page 7 line 4 and figure 1).

With regards to claim 1, Rossau et al teaches and claims a method of detecting a prokaryotic microorganism in a biological sample by hybridization to probes from the spacer region between the rRNA genes (see abstract and claim 13). Rossau et al teaches this region is between the 16S rRNA and 23S rRNA genes (see column 1 lines

19 and 20). The rRNA region taught by Rossau et al, is interpreted to be the ITS region of the specification. The method for hybridizing the ITS region of DNA is thus anticipated by Rossau et al.

With regards to claim 2, 3, and 4, Rossau et al teaches the isolation, amplification, and labeling of RNA or DNA from a biological sample, "is contacted with a membrane on which one or more oligonucleotide probes are dot spotted on a known location, in a medium enabling specific hybridization of the amplified target sequence and the probes on the membrane" (see column 22 lines 50-63). Rossau et al further teaches the use of a microtiter dish, which is a microplate. The specification does not define microarray. The broadest reasonable interpretation of microarray is a solid support to which 2 or more probes are attached, this would include a membrane with two or more probes which is taught by Rossau, as stated above. Absent a particular definition for the term "microarray" in the specification, Rossau is interpreted to teach a microarray as discussed above.

With regards to claim 5, Rossau et al teaches the isolation, amplification, and labeling of RNA or DNA from a biological sample, "is contacted with a membrane on which one or more oligonucleotide probes are dot spotted on a known location, in a medium enabling specific hybridization of the amplified target sequence and the probes on the membrane" (see column 22 lines 50-63). Rossau et al further teaches in example 1, the determination of *Neisseria gonorhoeae* and *Neisseria meningitides* by this method, (see table bottom column 30).

With regards to claim 7, Rossau et al teach the use of clinical samples, such as pus, sputum, blood, and urine (see column 6 lines 64-65). The specification does not specifically define identification of microorganisms in a living body, however specification does present an example of testing faeces to determine the constitution of gastrointestinal tract flora (see page 6 line 4). A broad interpretation of "identification of microorganisms in a living body" would be encompassed by Rossau's teaching of testing clinical samples. Rossau thus anticipates claim 7.

With regards to claim 8, Rossau et al teaches the use of samples including, environmental samples and bacterial colonies (see column 6 lines 63-67).

Response to Arguments

4. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the entire 16S rRNA and 23S rRNA sequence is used for conducting identification of the microorganism") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further the specification suggests that an ITS region or ITS DNA corresponds to the region between the 16S and 23S rRNA in Figure 1, not the "entire 16S and 23S rRNA" as argued.

Further "an" ITS region would include ITS1, ITS2, or fragments thereof.

Rossau teaches hybridization with probes derived from the 16S-23S rRNA spacer region for detection of bacterial strains (see column 3, lines 35-50). Therefore Rossau teaches using hybridization of DNA corresponding to an ITS region.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rossau et al (US Patent 5945282) in view of Balch (US Patent 6083763).

Rossau et al teaches the isolation, amplification, and labeling of RNA or DNA from a biological sample, "is contacted with a membrane on which one or more oligonucleotide probes are dot spotted on a known location, in a medium enabling specific hybridization of the amplified target sequence and the probes on the membrane" (see column 22 lines 50-63). Rossau does not teach the identification of microorganisms from food (claim 6).

However, with regards to claim 4, Balch teaches a system for monitoring food for microorganisms that is fast, cost effective system for quantitative analysis of analytes (see column 38 lines 40-43).

Therefore it would be prima facie obvious for one of ordinary skill in the art at the time the invention was made to improve Rossau's method of detecting microorganisms to include quantitative analysis of microorganisms in food samples taught by Balch. The ordinary artisan would be motivated to improve Rossau's method to include Balch's system of method because Balch teaches the system allows fast analysis (see column 38 line 56), simultaneous microbial monitoring (see column 38 line 63), minimal labor and training (see column 39 line 1), and minimal equipment (see column 39 line 6) of microorganisms in food.

Response to Arguments

7. The response traverses the rejection. The response asserts for the reasons presented for Rossau the rejection is improper. In addition the response asserts that Balch merely discloses a molecular analysis system and not one based on DNA.

This argument has been considered but is not convincing because Balch teaches, " An example would be a ribosomal RNA probe based assay in which nucleic acid probes-based assay in which nucleic acid probes serving as biosites...(see column 38, lines 43-44). Balch thus teaches an analyzing assay for detecting microorganisms in food using nucleic acids, which includes DNA. Thus the combination of Rossau and Balch would have been obvious to monitor microorganisms in food taught by Balch using the assay of Rossau.

Thus for the reasons above and those already of record, the rejection is maintained.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rossau et al (US Patent 5945282) in view of Carrino et al (US Patent 6238868).

It is noted that the microarray of claim 4 is interpreted as an addressable microchip.

Rossau et al teaches the isolation, amplification, and labeling of RNA or DNA from a biological sample, "is contacted with a membrane on which one or more oligonucleotide probes are dot spotted on a known location, in a medium enabling specific hybridization of the amplified target sequence and the probes on the membrane" (see column 22 lines 50-63). Rossau does not teach the use of an addressable microchip for microorganism detection (claim 4).

However, Carrino et al teaches identification of bacteria species by use of addressable microchip (see example 1, columns 21 and 22, and figure 3c). Carrino teaches an addressable microchip greatly reduces the need for strand separation, allows multiple samples to be analyzed, allows targeting of nucleotides to various locations, and inhibits the formation of double stranded nucleic acids (see column 22 lines 1-12).

Therefore it would be prima facie obvious for one of ordinary skill in the art at the time of the invention to improve the method of microorganism detection taught by Rossau by use of the addressable microchips taught by Carrino because addressable microchips reduce the need for strand separation, allow multiple samples to be analyzed, allow targeting of nucleotides to various locations, and inhibit the formation of double stranded nucleic acids. The ordinary artisan would be motivated to improve

Rossau's method because Carrino teaches addressable microchips reduce the need for strand separation, allow multiple samples to be analyzed, allow targeting of nucleotides to various locations, and inhibit the formation of double stranded nucleic acids

Response to Arguments

9. The response traverses the rejection. The response asserts for the reasons present for Rossau, and further asserts, "Applicant has carefully reviewed Carrino et al and respectfully submits that while Carrino et al. may disclose the use of a microchip, the method and apparatus of Carrino et al selectively operates on the particular strains that include a specific allele and is an SDA method."

This argument has been reviewed but is not convincing because Carrion teaches, " detection of a single nucleic acid in a test sample was performed using a common locus (16S rRNA) shared by different bacterial species" (see column 22, lines 20-23). Carrino thus teaches a method that is not limited to specific alleles.

Further Rossau teaches a DNA assay and Carrino was used to demonstrate that it would have been prima facie obvious to the ordinary artisan to incorporate the use of a microarray with Rossau's method. Thus SDA and selective probes taught by Carrino, are not limitations read into the prima facie obvious rejection.

Thus for the reasons above and those already of record, the rejection is maintained.

Summary

No claims are allowed over prior art cited.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

1/12/07
Primary Examiner